National Institutes of Health
Office of Research on Women's Health
Putting science to work for the health of women

NIH Clinical Trial Inclusion Checklist for PIs

- ☐ Describe plans for the inclusion of women and individuals from racial and/or ethnic minority groups, justify exclusions, and provide an enrollment form. See the General Application Guide for NIH Grants and Other PHS Agencies, and any instructions in the specific Notice of Funding Opportunity (NOFO) to which you are applying.

- ☐ For NIH-Defined Phase III clinical trials:
  - ☐ Explain whether the intervention is expected to produce clinically relevant differences based on sex and race and/or ethnicity.
  - ☐ Provide description of strategies for conducting a valid analysis by sex and race and/or ethnicity (See Valid Analysis for NIH-Defined Phase III Clinical Trials.)

- ☐ Justify the proposed age range of the participants and any age-based exclusions (See the Inclusion Across the Lifespan Policy and §2038(H) of the 21st Century Cures Act.)

- ☐ If pregnant women are included in the clinical trial, ensure protections and requirements are fulfilled as prescribed in 45 CFR 46, Subpart B.

- ☐ Update annual progress report with current enrollment and progress of valid analysis.

- ☐ For NIH-Defined Phase III clinical trials, provide results of valid analysis:
  - ☐ Report results of valid analysis in the Research Performance Progress Report (RPPR) Project Outcome.
  - ☐ For Phase IIIs that are applicable clinical trials (ACTs), report results in ClinicalTrials.gov.

For more information, please see the
NIH ORWH Inclusion Toolkit at https://orwh.od.nih.gov/toolkit.